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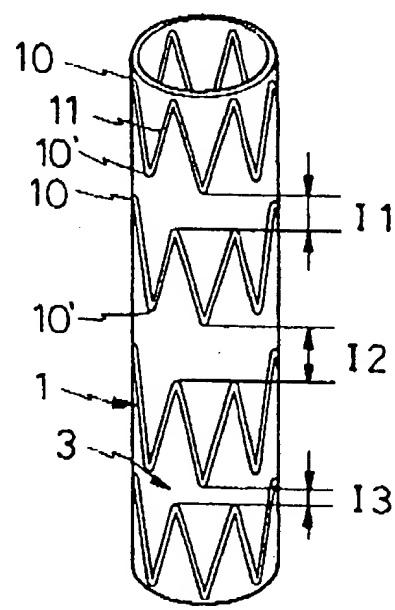
(54) Flexible self-expandable stent and method for making the same

(57) Disclosed is a zig-zag type stent sheathed by an elastic rubber member including at least two zig-zag units (1) spaced at fixed intervals, and a cover member (3) which sheaths the zig-zag units and acts as connecting means such that the stent does not require separate connecting means between the zig-zag units and the stent is cylindrically formed. Further, spacing between the zig-zag units is determined using the following formula:

$$l=2\pi d \frac{\theta}{360}/(\eta-1)$$

where, l is the interval between the zig-zag units which can be increased or decreased by 50%, d is a diameter of the stent, θ is a curvature angle of the stent, and η is the number of units.

FIG. 1



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Description

Field of the Invention

The present invention relates to a stent, and more particularly, to a flexible self-expandable stent and a method for making the same which can provide improved flexibility so that when the stent is disposed in curved lumina it can flexibly correspond to curvature of the lumina and prevent the reverse flow of foodstuffs or fluid.

Background of the Invention

Generally, stents are medical devices used to enlarge lumina of internal organs or blood vessels narrowed by, for example, disease, injury, or surgical operations. Such stents are normally cylindrically shafted and are broadly divided into the following two types: 1) stents having a predetermined amount of elasticity such that they can contract when external force is applied and self-expand when the external force is removed, and 2) stents made of plastic material such that after they are expanded from contracted states, maintain their expanded states.

With regard to the insertion of the above stents in lumina, a widely-used stent insertion device is utilized to allow for easy positioning of the stent. The explanation of this procedure will be omitted herein as this process is well known to those skilled in the art.

U.S. Patent No. 5,330,500 discloses a stent which, as shown in Fig. 8, comprises a plurality of cylindrical zig-zag elastic units 12, which contract when external force is applied and reexpand when the external force is removed, and a plurality of connecters 13 for connecting the zig-zag elastic units 12 to maintain the same in a cylindrical shape.

Although such a stent utilizing the above zig-zag units 12 attached by the connectors 13 remains in a constant and forceful expanded state, the stent is not flexible nor is it very effective when used to expand lumina which have collapsed. And when used in lumina which are curved in shape, the stent cannot be gently curved, resulting in the zig-zag units 12 and connectors 13 pressing too hard on inside walls of lumina such that inflammation and other complications occur.

Referring to Fig. 9, there is shown a schematic view of another prior art stent positioned in a curved lumen. As shown in the drawing, this stent includes a plurality of zig-zag units 101; a plurality of thread connectors 102 which connect the zig-zag units 101, and a cylindrical cover member 103 made of polyethylene material and which covers the zig-zag units 101 and the connectors 102.

However, the above stent has the drawback of blocking the passageway when used on curved lumina. That is, because the zig-zag units 101 are connected using the thread connectors 102 without any space therebetween and both the zig-zag units 101 and connectors 102 are covered with the cover member 103, when the stent is disposed in a curved lumen, the stent does not gently curve to correspond to a curvature of the lumen, but folds or creases as shown in the drawing so that the passage of the stent, and, thus, the lumen is blocked.

In addition, all prior art stents have the drawback of not having means to prevent the reverse flow of foodstuffs and fluids. Although the human body has natural mechanisms to inhibit the reverse flow of foodstuffs and fluids in the area, for example, where the stomach and esophagus meet, when using the prior art stent in this location it is possible that the esophagus will become damaged because of the reverse flow of acidic foodstuffs and liquids. Further, it is possible that reversed fluid will enter the lungs, leading to lung disease. It is, therefore, not viable to utilize the conventional stent in areas where foodstuffs and liquids need to be prevented from flowing in a reverse direction.

In addition, in the prior stents, the zig-zag units are welded such that each zig-zag unit comes to be formed in a single, integrally formed piece having a plurality of straight sections having a plurality of bends. During the welding process, it is common to use lead material. The lead material, however, can become oxidized within the human body resulting in heavy metals infecting the human body.

Summary of the Invention

The present invention is made in an effort to solve the above described problems of the prior art.

It is a first object of the present invention to provide a stent which provides improved flexibility so that when it is disposed in curved lumina the stent can follow a curvature of the lumina and not block a passageway of the same.

To achieve the above first object, the present invention provides a stent comprises:

at least two radial elastic cylindrical units; and
a cylindrical cover fixing member for sheathing and fixing the radial elastic cylindrical units without connecting means,

wherein the radial elastic cylindrical units are fixed by and disposed on the cylindrical cover such that adjacent ends

of each cylindrical units are spaced at predetermined intervals along the longitudinal. axis, and through the flexibility and elasticity of the cylindrical cover fixing member, the expanding and contracting of the cylindrical units is compensated for.

Each of the units is designed in a closed zig-zag configuration having a series of straight sections having bends in a cylindrical shape.

Preferably, the cylindrical cover fixing member is made of a material having flexibility and elasticity.

Preferably, the cylindrical cover fixing member is made of polymer materials.

Also preferably, the interval is determined within a range from 0.5l to 1.5l, in which the l is determined according to the following formula,

$$l=2\pi d\frac{\theta}{360}/(\eta-1)$$

where, l is the interval;
d is a diameter of the stent;
θ is a curvature angle of the stent; and
η is the number of units.

Further preferably, the interval is selected within a range from lmm to 20mm.

It is a second object of the present invention to provide a stent which, when is disposed in lumina, prevents the reverse flow of foodstuffs or fluid so as to prevent the esophagus and lungs from becoming harmed.

To achieve this second object, the stent further comprises a reverse flow preventing means for preventing foodstuffs or fluids from being reversed from a downstream side to an upstream side.

The reverse flow preventing means comprises a trileaflet valve member or a bileaflet valve member which open or close in unison.

Preferably, the reverse flow preventing means includes an opening portion to allow gases to escape therethrough.

Also preferably, the reverse flow preventing means is made of elastic and flexible material

Further preferably, the reverse flow preventing means is made of parts from living organisms such as a valve from a pig or a pericardium from a cow.

It is a third object of the present invention to provide a stent which prevents the occurrence of a dangerous situation caused by harmful material, such as lead, entering the human body as in the prior art.

To achieve this object, each of the units is designed in an opened zig-zag configuration having a series of straight sections being having bends in a cylindrical shape, in which open ends of the unit are not jointed but disposed to be adjacent.

According to another aspect, the present invention provides a method for making a flexible self-expandable stent, comprising the steps of:

preparing a cylindrical film made of elastic material and having an longitudinal axis;
attaching more than two elastic units having a diameter which is the same as that of the cylindrical elastic film on an outer or inner wall of the cylindrical elastic film, said units being spaced from each other in the longitudinal axis at predetermined intervals;
depositing the cylindrical elastic film and the units with polymer solution; and
hardening the deposited solution.

Preferably, the depositing step is performed by soaking the cylindrical elastic film with the units into the polymer solution.

Brief Description of the Drawings

The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate an embodiment of the invention, and, together with the description, serve to explain the principles of the invention:

Fig. 1 is a perspective view of a stent according to a preferred embodiment of the present invention;
Fig. 2 is a schematic view showing the stent depicted in Fig. 1 applied to a curved lumen;
Fig. 3 is a schematic view illustrating spacing between elastic units of the stent shown in Fig. 1;
Fig. 4 is a perspective view illustrating a stent where a reverse-flow preventing means according to an embodiment of the present invention is applied;
Fig. 5 is a perspective view illustrating the reverse-flow preventing means shown in Fig. 4;
Fig. 6 is perspective view illustrating a reverse-flow preventing means according to another embodiment of the

present invention;

Fig. 7 is a perspective view illustrating a stent according to another embodiment of the present invention;

Fig. 8 is a schematic view illustrating a prior stent; and

Fig. 9 is a schematic view illustrating another prior stent.

Detailed Description of the Preferred Embodiments

Preferred embodiments of the present invention will now be described in detail with reference to the accompanying drawings.

Referring first to Figs. 1 and 2, a stent according to a preferred embodiment of the present invention includes two or more cylindrical radial elastic units 1, and a cylindrical cover fixing member 3 sheathed over the elastic units 1 to fix the units 1 in a cylindrical shape. That is, the cover fixing member 3 acts as connecting means connecting the elastic units 1 such that separate connecting means, as in the prior art, is unneeded. Preferably, each of the units 1 has a length within a range from 10mm to 20mm.

The elastic units 1 are covered by the cover fixing member 3 according to the following manner.

A cylindrical elastic film made of elastic material and having a diameter substantially the same as of the elastic units 1 is first prepared. More than two elastic units 1 are attached on an outer or inner wall of the elastic film. The cylindrical film with the elastic units 1 is then soaked in an elastic material solution which, after drying, completes the forming of the cover fixing member 3 on the elastic units 1. It should be noted, however, that the covering method is not limited to the above process.

The elastic units 1 contract when external force is applied thereon, allowing the stent to be easily inserted within a stent insertion device and expand when the stent insertion device is removed, thereby expanding the lumen. That is, each of the elastic units 1 is made in a zig-zag shape having a series of straight sections 11 having a plurality of upper and lower bends 10 and 10'. The elastic units 1 are fixed by the cylindrical cover fixing member 3 such that the elastic units 1 are spaced apart from each other. Namely, an imaginary circle connecting the lower bends 10' of one elastic unit 1 is spaced from an imaginary circle connecting the upper bends 10 of another adjacent elastic unit 1 in intervals l1, l2 and l3. The intervals l1, l2 and l3 can be identical to, or different from, each other. Since the cylindrical cover fixing member 3 is sheathed over the elastic units 1 such that the cylindrical cover fixing member 3 and the elastic units 1 are integrally formed and take on a cylindrical shape, and the cover fixing member 3 is made of elastic material, the stent can be placed in a curved lumen and easily follow a curvature of the same. As shown in Fig. 2, when the stent according to the present invention is placed in a lumen, the stent is gently curved corresponding to the curvature of the same.

The above is possible because the distance between adjacent upper and lower bends 10 and 10' of each unit 1 at an outer portion of the stent (with respect to the curving direction) enlarges, while the distance between the adjacent upper and lower bends 10 and 10' of each unit 1 at an inner portion of the stent (with respect to the curving direction) decreases. As a result, the stent can be gently curved as shown in fig. 2.

Therefore, it is preferable to make the cylindrical cover fixing member 3 using polymer material such as polyurethane, polyethylene, polyproplene, polyisoplene, polybutadiene, polycloloplene, or polystilene, all of which have the elasticity to allow for the above flexibility. The following chart lists the requirements that should be met by the material used for the fixing member.

Item	Requirements
Tensile Modulus	300-3000 PSI When 50% Extended
Ultimate Tensile Strength	Under 4000 PSI
Tear Strength	Over 400 Die "c" PLI
Flexural Modulus	Under 10,000 PSI
Flexural Strength	Under 300 PSI

Determination of the interval l between adjacent upper and lower bends of adjacent elastic units of the zig-zag type stent according to a preferred embodiment of the present invention will be described hereinafter with reference to Fig. 3.

The interval l is determined using the following formula.

$$l=2\pi d\frac{\theta}{360}/(\eta-1)$$

where:
d is the diameter of the stent;
θ is the curvature angle of the stent; and
η is the number of units.

The following is the computation method of the above formula.

When the stent is inserted in a curved lumen, the stent comes to be formed having a curvature radius as shown in Fig. 3. It is preferable that the interval l is determined by the difference between a small arc l_1 on an inside of the curve, and a large arc l_2 on an outside of the curve.

Accordingly, if r is a curvature radius of the small arc,

$$l_1 = r\theta \qquad (1),$$

and

$$l_2 = (r + d)\,\theta \qquad (2)$$

If (1) is subtracted from (2),

$$l_2 - l_1 = (r + d)\theta - r\theta$$

$$= d\theta \qquad (3)$$

Therefore, the interval l between the zig-zag units 1 is calculated by dividing (3) by the number of folds

$$l = d\theta\,/\,(\eta\text{-}1) \qquad (4)$$

As

$$\theta = 2\pi\theta/360°\ ,$$

$$S=2\pi d\frac{\theta}{360}/\,(\eta\text{-}1)$$

The interval l between the zig-zag units 1 calculated using the above formula can be changed ±50% according to the lumina inside which the stent is inserted. That is, the preferable interval range Pl which can be applied to the stent of the present invention can be determined as follows:

$$0.5Xl<Pl<1.5Xl$$

When using the above formula to determine the interval between adjacent upper and lower bends 10 and 10' of adjacent elastic units 1, manufacturing of the stent is easy and can be done to accurately match the diameter and curvature of lumina.

Referring now to Figs. 4 and 5, there is provided reverse flow preventing means in the stent of the present invention. The reverse flow preventing means 7 is realized through a trileaflet polymer valve.

As shown in Fig. 4, when assuming that an upper side of the stent (in the drawing) is upstream and a lower side is downstream, with regard to the direction in which foodstuffs and fluids flow, the reverse flow preventing means 7 is mounted on a downstream end.

The reverse-flow preventing means 7 includes a first plate 71, one end and sides of which are attached to an inner wall of the stent with a free end of the same progressively positioned toward a center axis of the stent and an attachment area of the first plate 71 utilizing roughly one-third of a circumference of the stent Inner wall; a second plate 73, attached similarly as the first plate 71 and utilizing another one-third of the stent inner wall circumference; and a third plate 75,

also attached similarly as the first plate 71 and utilizing a remaining one-third of the stent inner wall circumference. Accordingly, the first, second, and third plates 71, 73 and 75 are adjacent to each other on free ends thereof as shown in the drawings.

As a result of the above structure, when foodstuffs or liquids flow from the upstream side to the downstream side by gravity or other forces, the plates 71, 73 and 75 are pushed aside such that an opening is created to allow the foodstuffs or liquids to pass therethrough. However, if foodstuffs or liquids flow in the reverse direction (i.e., downstream to upstream), the free ends of the plates 71, 73 and 75 are pushed together such that a seal is provided to prevent the flowing of foodstuffs or liquids.

It is preferable that the plates 71, 73 and 75 are made of a material similar to that used for the cylindrical cover fixing members 3. That is, it is preferable that the plates 71, 73, and 75 are made of polyethylene, polyurethane or other such resinous materials such that the material allows the plates 71, 73 and 75 to freely open and close and is not harmful to the human body.

In addition, in the preferred embodiment of the present invention, although the reverse flow preventing means 7 is attached to one end of the stent, it is possible to attach the reverse flow means 7 anywhere along the inside of the stent, and it is also possible to attach the stent protruding outward from an end thereof.

Also, as shown in Figs. 4 and 5, an opening portion 77 is formed between the plates 71, 73 and 75 at approximately the center axis of the stent. The formation of the opening portion 77 is done for allowing gases to escape therethrough when the stent is applied to the area between the stomach and esophagus.

Referring now to Fig. 6, there is shown a reverse flow preventing means 7' according to another preferred embodiment of the present invention. The reverse flow preventing means according to this embodiment is realized through a bileaflet polymer valve. As shown in the drawing, the bileaflet polymer valve includes first and second plates 72 and 74. One end and sides of the plates 72 and 74 are attached to the inner wall of the stent while other ends are left unattached and progressively positioned toward the center axis of the stent such that free ends of the plates 72 and 74 come to be adjacent to each other.

Each of the elastic units 1 described above is made by joining ends of the units 1 by welding using, for example, lead. Therefore, when the stent is placed in lumina, it is possible that harmful material can enter the human body.

To solve this problem, according to another embodiment of the present invention, the elastic units, as shown in Fig. 7, are designed having a zig-zag shape wherein opened series of straight sections are joined by bends. That is, opposite end straight sections 11' and 11" of the sections 11 are not joined to each other but disposed adjacent to each other, providing an overlapping portion 15 such that welding is not necessary.

As a reverse flow preventing means is provided in the stent of the present invention, it is possible to safely apply the stent to areas requiring the prevention of the reverse flow of foodstuffs and liquids such as the area between the stomach and esophagus. As a result, medically dangerous situations caused by the reverse-flow of foodstuffs and liquids can be circumvented.

Further, because the present invention provides a stent having improved flexibility, when the stent is disposed in curved lumina the stent can follow a curvature of the lumina and not block a passageway of the same.

Finally, as welding is not needed for the elastic units, there is prevented the occurrence of a dangerous situation caused by harmful material, such as lead, entering the human body as in the prior art.

While this invention has been described in connection with what is presently considered to be the most practical and preferred embodiment. it is to be understood that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

Claims

1. A flexible self-expandable stent having a longitudinal axis, comprising:

   at least two radial elastic cylindrical units (1); and
   a cylindrical cover fixing member (3) for sheathing and fixing the radial elastic cylindrical units,

   wherein the radial elastic cylindrical units are fixed by and disposed on the cylindrical cover fixing member such that adjacent ends of each elastic cylindrical unit are spaced at predetermined intervals (13) along the longitudinal axis.

2. A flexible self-expandable stent having a longitudinal axis, wherein, if the stent has more than three radial elastic cylindrical units (1), the intervals (13) between the units are identical to, or different from each other.

3. A flexible self-expandable stent according to claim 1, wherein each of the units (1) is designed in a closed zig-zag configuration having a series of straight sections (11) being joined by bends (10) in a cylindrical shape.

4. A flexible self-expandable stent according to claim 1, wherein each of the units is designed in an opened zig-zag configuration having a series of straight sections (11', 11") being joined by bends in a cylindrical shape, in which open ends of the unit are not jointed but disposed to be adjacent.

5. A flexible self-expandable stent according to claim 1, 3 or 4, wherein the cylindrical cover fixing member (3) is made of a material having flexibility and elasticity.

6. A flexible self-expandable stent according to claim 5, wherein the cylindrical cover fixing member (3) is made of polymer materials.

7. A flexible self-expandable stent according to any one of claims 1 and 3 to 6, wherein the interval (13) is determined within a range from 0.5l to 1.5l, in which the l is determined according to the following formula,

$$l=2\pi d\frac{\theta}{360}/(\eta-1)$$

where, l is the interval;
d is a diameter of the stent;
θ is a curvature angle of the stent; and
η is the number of units.

8. A flexible self-expanding stent according to claim 7, wherein the interval (13) is selected within a range from 1mm to 20mm.

9. A flexible self-expanding stent according to any one of claims 1 and 3 to 8 further comprising a reverse flow preventing means (7) for preventing foodstuffs or fluids from being reversed from a downstream side to an upstream side.

10. A flexible self-expanding stent according to claim 9, wherein the reverse flow preventing means (7) comprises a trileaflet valve member.

11. A flexible self-expanding stent according to claim 10, wherein the trileaflet valve member (7) includes a first plate (71), one end and sides of which are attached to an inner wall of the stent with a free end of the same progressively positioned toward a center axis of the stent and an attachment area of the first plate utilizing roughly one-third of a circumference of the stent inner wall, a second plate (73) attached similarly as the first plate and utilizing another one-third of the stent inner wall circumference, and a third plate (75) also attached similarly as the first and second plates and utilizing a remaining one-third of the stent inner wall circumference.

12. A flexible self-expandable stent according to claim 9, wherein the reverse flow preventing means (7') comprises a bileaflet valve member.

13. A flexible self-expandable stent according to claim 12, wherein the bileaflet valve member (7') includes first and second plates (72, 74), one end and sides of the plates being attached to an inner wall of the stent while other ends being left unattached and progressively positioned toward the longitudinal axis of the stent such that free ends of the plates come to be adjacent to each other.

14. A flexible self-expandable stent according to claim 9, wherein the reverse flow preventing means (7) includes an opening portion (77) to allow gases to reversely escape therethrough.

15. A flexible self-expandable stent according to any one of claims 9 to 14, wherein the reverse flow preventing means (7) is made of elastic and flexible material.

16. A flexible self-expandable stent according to any one of claims 9 to 15, wherein the reverse flow preventing means (7) is made of parts from living organisms such as a valve from a pig or a pericardium from a cow.

17. A method for making a flexible self-expandable stent, comprising the steps of:

preparing a cylindrical film made of polymer material (3) and having a longitudinal axis;
attaching more than two elastic units (1) having a diameter which is the same as that of the cylindrical elastic film on an outer or inner wall of the cylindrical elastic film, said units being spaced from each other in the longitudinal axis at predetermined intervals (13);
depositing the cylindrical elastic film and the units with polymer solution; and
hardening the deposited solution.

18. A method for making the flexible self-expandable stent according to claim 17, wherein the depositing step is performed by soaking the cylindrical elastic film with the units into the polymer solution.

FIG. 1

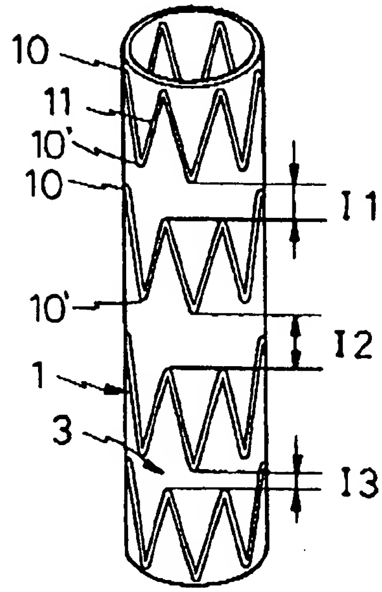


FIG. 2

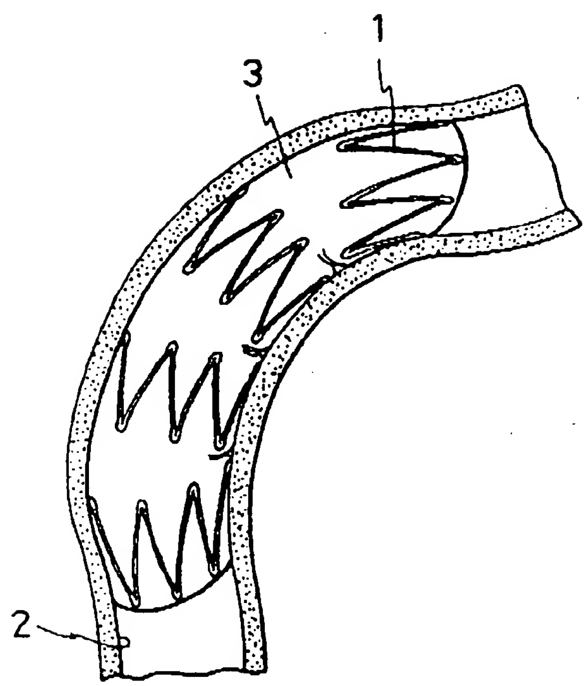


FIG. 3

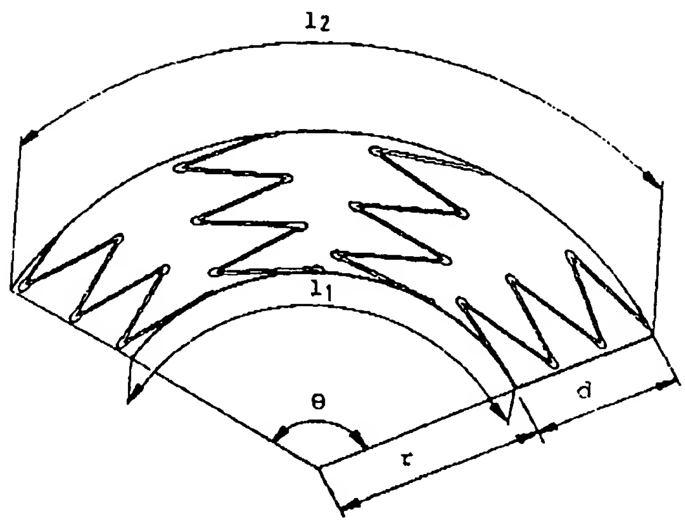


FIG. 4

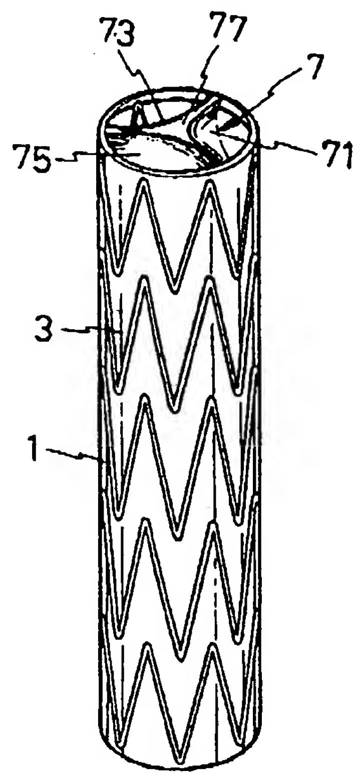


FIG. 5

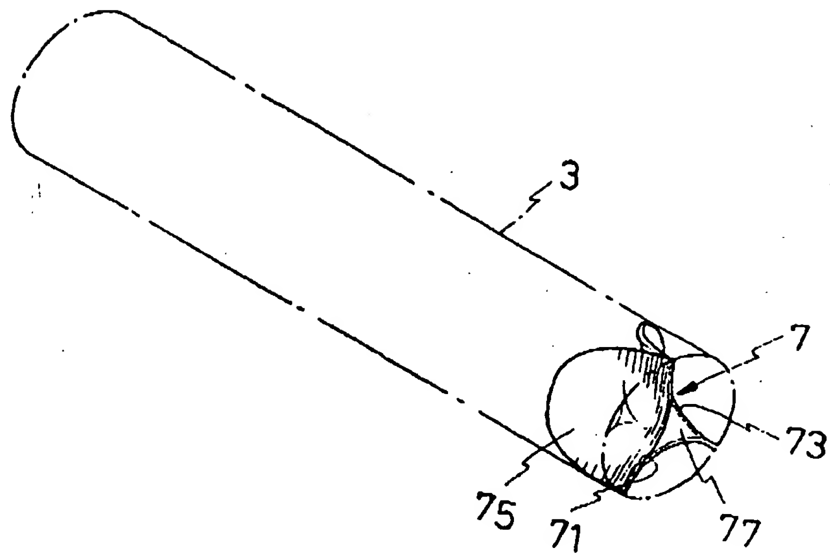


FIG. 6

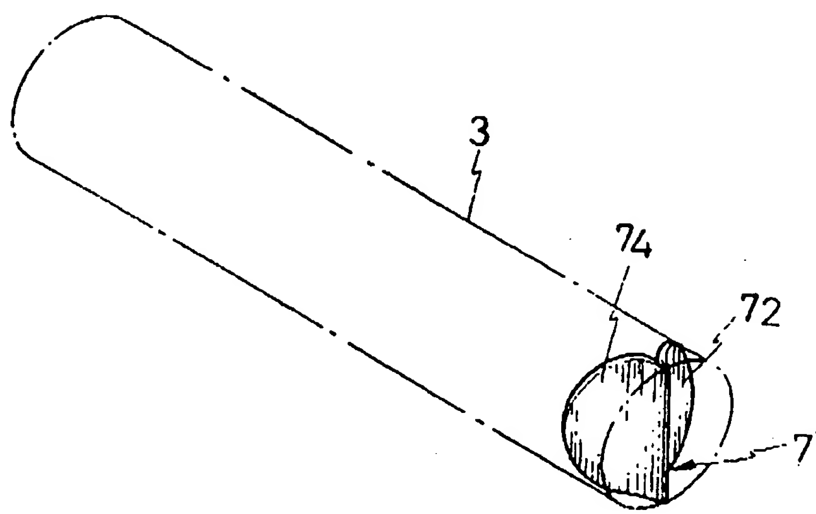


FIG. 7

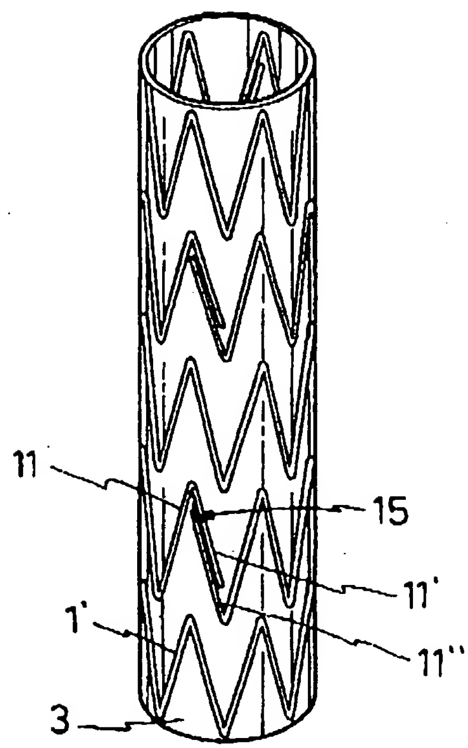


FIG. 8
(PRIOR ART)

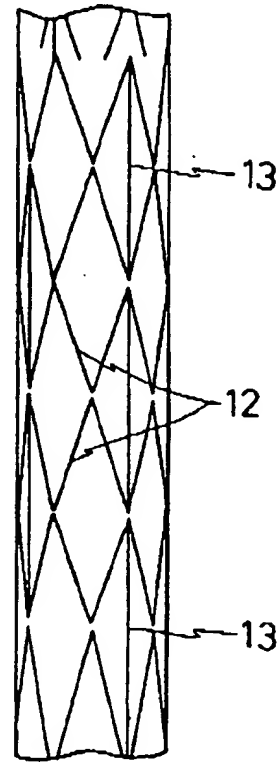
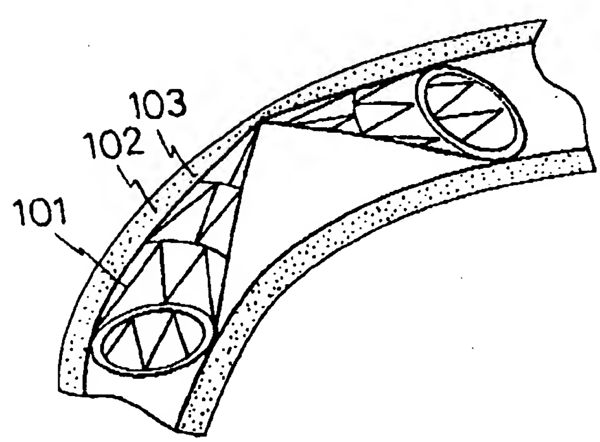


FIG. 9
(PRIOR ART)



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